IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ADVANCED CARDIOVASCULAR SYSTEMS, INC. and GUIDANT SALES CORPORATION,	)	
Plaintiffs,	)	C. A. No. 98-80 (SLR) (Consolidated with C. A. No. 98-314 (SLR) and C. A. No. 98-316 (SLR))
v.	)	
MEDTRONIC VASCULAR, INC. and MEDTRONIC USA, INC.,	)	
Defendants.	)	

MEDTRONIC'S OPENING BRIEF IN SUPPORT OF ITS MOTION FOR NEW TRIAL PURSUANT TO FED. R. CIV. P. 59(a)

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April 18, 2005

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NATURE AND STAGE OF PROCEEDINGS

These consolidated cases were filed in Delaware in 1998 (D.I. 1 (Complaint filed 2/18/98)). Before trial, the Court granted summary judgment in favor of Advanced Cardiovascular Systems, Inc. and Guidant Sales Corporation (collectively, "ACS") on the claims of Medtronic Vascular, Inc. and Medtronic USA, Inc. (collectively, "Medtronic") for infringement of its Boneau patents and various state law claims relating to ACS's misuse of confidential information regarding the Boneau invention. (D.I. 544 & D.I. 546). From February 7 to 18, 2005, the Court held a 9-day trial on the remaining legal issues in the case, namely, ACS's claims that Medtronic's stents infringe the asserted claims of various ACS patents and Medtronic's counterclaim that ACS's patents are invalid as obvious and anticipated.[1] The Court has scheduled a two-day hearing for June 7 and 8, 2005, with respect to Medtronic's inequitable conduct claim.

Medtronic moved for judgment as a matter of law ("JMOL") at the close of ACS's case and again at the close of all evidence. (D.I. 598; Trial Tr. at 1678:19-1680:11 & Docket Entry of 2/16/05). ACS too moved for JMOL at close of all evidence. (D.I. 621, DI. 622 & Trial Tr. at 1680:12-1683:1). The Court denied the parties' JMOL motions with the exception of Medtronic's motion as to no infringement by equivalents and ACS's motion as to anticipation. (Docket Entry of 2/17/05 & Trial Tr. at 1739:28-

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[1] The asserted claims are claims 1, 4 and 12 of U.S. Patent No. 5,512,154 (the "'154 patent"); claims 5 and 8 of U.S. Patent No. 6,066,167 (the "'167 patent"); claims 1, 3 and 11 of U.S. Patent No. 6,066,168 (the "'168 patent"); and claims 1, 2, 3 and 9 of U.S. Patent No. 6,432,133 (the "'133 patent"). The text of the asserted claims is set forth in Exhibit A to this brief.

As referred to here, the "Lau patents" means these patents in suit (and the asserted claims) as well as, to the extent appropriate in context, other patents issuing from the same original application (Ser. No. 07/783,558, filed Oct. 28, 1991).

1740:1). On February 18, the jury returned a verdict that the ACS patents are not invalid and that Medtronic's accused products infringe the asserted claims. (D.I. 629). The Court has not yet entered judgment on the jury verdict.

By Order dated March 11, 2005, the Court directed the parties to file any post-trial motions by April 18, 2005. (D.I. 643). This is Medtronic's opening brief in support of its motion for new trial pursuant to Fed. R. Civ. P. 59(a).

SUMMARY OF ARGUMENT

Medtronic respectfully cites the following six separate and independent grounds, each of which justifies the grant of a new trial in this case:

First, a new trial is needed because, consistent with the specification and prosecution history of the Lau patents, the jury should have been instructed that the cylindrical elements of the claimed invention are formed by an undulating pattern made up of a combination of U-shaped, W-shaped and Y-shaped members. In the alternative, the jury should have been instructed that, though connected, the cylindrical elements also must be spaced apart. Because the jury verdict was based on an incorrect claim construction, if the Court denies judgment as a matter of law on this issue, a new trial should be granted.

Second, a new trial should be granted because the Court excluded much relevant and probative evidence concerning Medtronic's invalidity claim. The Court excluded most of the testimony of Michael Boneau regarding his early stent-related work, his idea of connecting stents, and meetings he had with ACS before Lilip Lau came up with his invention. The Court also excluded much of the proffered testimony of Mr. Lau, Farhad Khosravi, and William Hartigan. Excluding this evidence allowed ACS to create

the false impression that Mr. Lau and his co-inventors invented something new and revolutionary, that had never been thought of before. Based on the incomplete information ACS was allowed to present, ACS was able to pose the rhetorical question to the jury: "If this invention was so obvious, why was ACS ahead of everyone else in commercializing it?" The Court's rulings precluded Medtronic from providing the answer: "Because only ACS had access to Mr. Boneau's small, sinusoidal element," and precluded Medtronic from offering evidence as to what it was that Lau and Hartigan actually invented.

Third, the Court erred in excluding evidence of incorrect statements made to the Patent Office during the prosecution of the Lau patents. ACS repeatedly pointed out during trial that its patents had been reviewed by the Patent Office. Medtronic should have been permitted to show that the Patent Office had incorrect information about the prior art when issuing the patents.

Fourth, Medtronic's anticipation defense should have gone to the jury. Medtronic's expert, Dr. Sunil Saigal, provided testimony from which a reasonable juror could have concluded that at least one prior art patent cited by Medtronic anticipated the Lau patents.

Fifth, the Court improperly precluded Medtronic from supplementing Dr. Saigal's expert report or otherwise relying on the Court's ruling the Palmaz prior art patent disclosed a stent made up of "straight segments . . . connected at their ends . . . to form a circular band" which are then "connected to two straight segments . . . that attach adjacent bands." Having determined that ACS did not infringe the Boneau patents based on certain factual findings (with which Medtronic disagreed, but which it understood to

be the law of this case), the Court should have permitted Medtronic to rely on that same ruling in addressing the validity of the Lau patents.

Sixth, there can be no dispute that Medtronic was prejudiced in having to present evidence on a key claim construction issue to the jury, only to have the jury then learn that ACS had "prevailed" on that issue. By proceeding in this manner, the Court implicitly signaled to the jury that ACS's expert was correct and Medtronic's expert was wrong, and the jury undoubtedly drew improper inferences adverse to Medtronic.

The overwhelming, cumulative effect of these errors counsels decisively in favor of granting Medtronic a new trial on both infringement and invalidity.

STATEMENT OF FACTS

The facts related to each of the grounds upon which Medtronic moves for new trial are addressed in the corresponding sections of the argument, below.

ARGUMENT

I. THE APPLICABLE LEGAL STANDARD

Rule 59 of the Federal Rules of Civil Procedure governs the grant of a new trial. Fed. R. Civ. P. 59. Under Rule 59, "[a]ny error of law, if prejudicial, is a good ground for a new trial." Wright, Miller & Kane, *Federal Practice and Procedure, Civil 2d* §2805 (1995). The Third Circuit has instructed that "[t]he decision to grant or deny a new trial is confided almost entirely to the discretion of the district court." *Blancha v. Raymark Indus.*, 972 F.2d 507, 512 (3d Cir. 1992) (citing *Allied Chem. Corp. v. Daiflon, Inc.*, 449 U.S. 33, 36 (1980)).

Errors justifying a new trial include jury instructions that misstate or insufficiently state the law, *Tex. Digital Sys., Inc. v. Telegenix, Inc.*, 308 F.3d 1193, 1201

(Fed. Cir. 2002), or the prejudicial admission of evidence that should not have been admitted or exclusion of evidence that should not have been excluded. *See, e.g., True N. Composites, LLC v. Trinity Indus., Inc.*, 191 F. Supp. 2d 484, 514 (D. Del. 2002). Once an error of law has been shown, a new trial must be granted unless "it is highly probable that [the erroneous ruling] did not affect the [objecting party's] substantial rights." *McQueeney v. Wilmington Trust Co.*, 779 F.2d 916, 928 (3d Cir. 1985).

Here, Medtronic can show that not one, but several errors of law affected its substantial rights, requiring the grant of a new trial.

II. IT WAS PREJUDICIAL ERROR TO CONSTRUE THE LAU PATENTS SO AS NOT TO REQUIRE SPACED APART CYLINDRICAL ELEMENTS.

In its renewed motion for judgment as a matter of law ("JMOL"), filed with this motion, Medtronic details why the Court's original construction of the term "undulating pattern" (requiring a combination of U-, W- and Y-shaped members) was correct, and why the Court's later construction ("wavelike") was not. Medtronic incorporates that discussion here by reference.

As explained in both the specification and file history, the asserted claims require cylindrical elements that are spaced apart. For the reasons set out in Medtronic's JMOL motion, the Court should have construed "undulating pattern" to require a combination of U-, W- and Y-shaped members to reflect this requirement. Alternatively, the Court should have construed other claim elements, such as "interconnected" and "connected," to include a requirement of spacing apart adjacent cylindrical elements. Respectfully, the failure to do either one was legal error.

The Court's decision clearly prejudiced Medtronic. As an initial matter, even ACS admitted that one of the accused products (the BeStent2) could not infringe the Lau patents under the original construction. (*See* Exh. B (2/3/05 F. Cottrell e-mail to Court)). More generally, however, as Medtronic's JMOL brief demonstrates, none of the accused stents infringes because none of them has either Y-shaped or W-shaped members (or any other structure spacing the cylindrical elements apart). A properly instructed jury could have concluded (and, indeed, must conclude) that there is no infringement because the U-shaped rings of Medtronic's stents are fused directly together, with no material added, and therefore, lack Y-shaped or W-shaped members.

Accordingly, and for the reasons set forth in detail in Medtronic's motion for JMOL, if the Court does not grant JMOL, it should order a new trial on infringement.

III. MEDTRONIC WAS PREJUDICED BY THE EXCLUSION OF MUCH OF THE TESTIMONY RELATING TO ITS OBVIOUSNESS DEFENSE

A. ACS Opened The Door To Testimony By Boneau And Others And Such Testimony Should Not Have Been Excluded

The Court excluded much of the evidence Medtronic sought to offer at trial to prove obviousness. As a result, ACS was able to tell a one-sided story of half-truths that improperly led the jury to believe that Lau and his co-inventors had invented something new. ACS opened the door by telling a "development" story about how its MultiLink stent purportedly revolutionized balloon angioplasty procedures overnight, but Medtronic was precluded from explaining that Mr. Boneau gave ACS the very idea (a sinusoidal structure that could be made very short) that made ACS's invention possible. Medtronic was also precluded from explaining that ACS had been the first to

commercialize the stent because it had access to Boneau's invention before that invention was publicly available, even to Medtronic.

The excluded testimony of Mr. Boneau, and that of ACS inventors Lilip Lau and William Hartigan, as well as ACS engineer Farhad Khosravi, would have established that ACS did not add anything non-obvious to the art and that ACS's MultiLink stent was very similar to the Boneau stent that preceded it. Mr. Boneau's testimony would also have helped elucidate the state of the relevant art and undercut ACS's attack on the accuracy of the statements in Mr. Boneau's patent (U.S. Patent No. 5,292,331 ("the '331 patent")).

All of these were proper subjects of testimony, the exclusion of which warrants a new trial.

B. The Court Excluded Significant Portions Of Mr. Boneau's Proffered Testimony

According to ACS, Mr. Boneau did "not appear to have any factual knowledge relevant to the issues currently in the case." D.I. 565 at 7. ACS was plain wrong.

1. Mr. Boneau's Testimony Could Have Helped The Jury Understand Why Other Stent Manufacturers Had Not Thought Of Connecting Short, Sinusoidal Elements

At trial, ACS argued it was the first company to come up with a stent that was both strong and flexible. On this basis, ACS argued that the Lau invention was a revolutionary advance in the field of coronary stenting. According to ACS's expert, Dr. Segal, connecting short, sinusoidally shaped rings was a new and non-obvious design breakthrough that marked a departure from earlier coronary stent designs:

> Q: All right. Let's do a recap of where we are if [sic: as] we get to the ACS patents. The group on the top that we talked about already, the Palmaz-type devices, Gianturco-type devices and the Boneau balloon expandable version. And then is it fair to characterize those as strong, but not very flexible?
>
> A: I think that would be a fair characterization, yes.
>
> Q: And the Gianturco device at the bottom was flexible, but not strong?
>
> A: Yes, that would be my opinion.
>
> Q: So there still wasn't anything that satisfied both aspects that people were looking for?
>
> A: At that point in time, there really was nothing that combined the two major aspects we were looking for [strength and flexibility].

(Trial Tr. at 404-405).

Indeed, Dr. Segal, returned to this theme over and over again. He later testified that various companies – including Johnson & Johnson, Cook, Medtronic and AVE – were trying to come up with a strong, flexible stent, but ACS won the "horse race." (Trial Tr. at 1585-1591). Dr. Segal explained his conclusion:

> A: What was really different [about the ACS invention was that] they kind of abandoned the stent philosophy and went with small cylindrical elements, things this [sic: that] were too small to function as stents and then hooked them together with connections to form a flexible stent.
>
> * * *
>
> A: It really revolutionized the practice [of cardiology] in many ways because we could now use this in places we couldn't get to before. We were doing things that were not beneficial to the patient.

(Trial Tr. at 1592-1593).

Had he been permitted to testify on the subject, Mr. Boneau could have told the jury facts from which it could have concluded that the MultiLink was not as revolutionary as ACS would have had them think. Mr. Boneau would have explained how he met with ACS in 1989 and again 1990 (before Mr. Lau filed his original patent application in October of 1991), told them about his sinusoidal ring, and provided them with not one, but two copies of his own patent application (which was filed in August 1989 and issued as the '331 patent in 1994). Mr. Boneau also could have told the jury that he discussed with ACS the idea of connecting single rings (with sutures), again, before Mr. Lau filed his patent application claiming connected rings.

Had the jury known that Mr. Boneau told ACS in 1989 and 1990 about his idea of connecting short, sinusoidal elements, or even just that he told ACS about the short sinusoidal elements disclosed in his patent application before it was issued and made public, the jury would have had a more accurate understanding of *why* ACS was able to commercialize its stent before others. Medtronic should have been allowed to tell the jury that ACS had a head start in Dr. Segal's "horse race." Because Medtronic was precluded from presenting this evidence to the jury, ACS was able to present a one-sided and misleading version of its development story and exaggerate the novelty of its own stent design. ACS was able to mischaracterize the impact of the Lau technology and leave the jury with the mistaken impression that ACS was the first to come up with a design that was both strong and flexible. This false impression significantly prejudiced Medtronic in the presentation of its case.

2. Mr. Boneau's Testimony About ACS's and Mr. Lau's Knowledge of The Boneau Stent Was Relevant To Secondary Considerations Of Non-Obviousness

A number of secondary considerations bear on whether an invention is obvious. These include: (1) a long-felt and unmet need in the art for the invention; (2) whether the invention was contrary to accepted wisdom of the prior art; (3) unexpected results and (4) independent invention by others. *Pechiney Rhenalu v. Alcoa Inc.*, 224 F. Supp. 2d 773, 800 (D. Del. 2002) (citing *Graham v. John Deere Co.*, 383 U.S. 1, 17-19 (1966); *Ruiz v. A.B. Chance Co.*, 234 F.3d 654, 667-68 (Fed. Cir. 2000)). "Against this background, the obviousness or nonobviousness of the subject matter is determined . . . [and] might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented. As indicia of obviousness or nonobviousness, these inquiries may have relevancy." *Graham*, 383 U.S. at 17-18. The testimony of Mr. Boneau excluded by the Court would have been directly relevant to at least some of these secondary considerations.

In *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530 (Fed. Cir. 1983), the Federal Circuit emphasized that:

> [i]t is jurisprudentially *inappropriate* to disregard *any* relevant evidence on any issue in any case, patent cases included. Thus evidence rising out of the so-called 'secondary considerations' *must always* when present be considered en route to a determination of obviousness. Indeed, evidence of secondary considerations may often be the most probative and cogent evidence in the record. It may often establish that an invention appearing to have been obvious in light of the prior art was not. It is to be considered as part of all the evidence, not just when the decisionmaker remains in doubt after reviewing the art.

Stratoflex, 713 F.2d at 1538-1539 (Fed. Cir. 1983) (emphasis added).

Here, the Court did just what *Stratoflex* cautioned against: it prevented Medtronic from introducing evidence to place the obviousness inquiry in its full and proper context. By precluding evidence relating to Mr. Boneau's relationship with ACS and Mr. Lau, the jury was prevented from evaluating validity based on all the facts concerning what was ***actually*** known in the prior art (as opposed to what is ***presumed*** to be known by the hypothetical person of ordinary skill). What the jury did ***not*** hear was that ACS did, in fact, have the benefit of knowing about Mr. Boneau's invention. Armed with that information, the jury might well have concluded, for example, that ACS's new stent design was ***not*** "contrary to accepted wisdom." It would also have understood that the work of Mr. Lau and others did ***not*** lead to "unexpected results." Finally, it would have more fully appreciated the impact of independent invention by others. Because the proffered testimony was probative of secondary considerations, it should have been admitted.

3. ACS's Other Objections To Mr. Boneau's Testimony Lacked Merit

In addition to contending that Mr. Boneau's testimony was irrelevant, ACS raised other objections equally lacking in merit. ACS argued that Mr. Boneau's testimony regarding his work with stents should be excluded because Medtronic had not asserted the Boneau suture stent as relevant prior art. (D.I. 565 at 4-5; 2/2/05 Tr. at 12-13). In fact, however, Mr. Boneau had testified about his work on suture-stents in at least six of a dozen depositions in this case. (D.I. 572 at 9; 2/2/05 Tr. at 21-22). ACS had known about Mr. Boneau's work with suture-stents since 2000.

ACS also argued that, in offering evidence of Mr. Boneau's interactions with ACS in the 1989 to 1990 time frame, Medtronic was attempting to "backdoor" its

previously dismissed trade secret and inventorship claims. (D.I. 565 at 6-7; 2/2/05 Tr. at 13-14). This attack on Medtronic's motivation was neither proper nor well founded. As Medtronic explained, it did not intend to raise issues of inventorship or misappropriation of trade secrets. (D.I. 572 at 6-7; 2/2/05 Tr. at 15-16). Rather, Medtronic offered the evidence relating to Mr. Boneau and his invention only to the extent that evidence properly bore on the question of the validity of the asserted claims. Mr. Boneau was practicing the relevant art at the relevant time. He is the inventor of the Boneau stent. The Boneau stent is prior art for purposes of obviousness (D.I. 572 at 7) (a fact which ACS did not contest (2/2/05 Tr. at 15:5-6)). ACS had access to his invention before others. All of this made Mr. Boneau's testimony relevant notwithstanding the fact that it potentially overlapped with subjects relevant to claims that the Court had dismissed. The fact that the evidence may have been relevant to more than one issue was not a proper rationale for excluding the evidence altogether.

C. Because Farhad Khosravi's Testimony Would Have Corroborated Mr. Boneau's On Key Points, The Court Erred In Excluding His Testimony

At trial, Medtronic also sought to introduce certain testimony of Farhad Khosravi – a former engineer who worked closely with Mr. Lau in developing ACS's MultiLink stent technology – to demonstrate that the Lau patents were obvious in light of Boneau. In fact, Medtronic intended to show that ACS's stents were nothing more than a series of short Boneau rings that were connected together, and that connecting Boneau rings would have been obvious to anyone involved in stent development. Particularly probative on this point was testimony by Mr. Khosravi regarding the similarities between the Bronco stent (the prototype MultiLink stent) and Mr. Boneau's stent. Specifically,

Medtronic sought to introduce Mr. Khosravi's testimony that "if you make the – make Boneau out of a tube, make the segments short enough, have the number of segments closely enough connected to each other, then effectively it's a Bronco stent." (D.I. 596, Ex. D).

ACS contended that this testimony was only relevant to Medtronic's trade secret claim and to meetings that ACS had with Mr. Boneau. (D.I. 595). This is wrong. Mr. Khosravi's testimony would have been relevant, for many of the same reasons Mr. Boneau's testimony was relevant, to Medtronic's obviousness case. In addition, however, Mr. Khosravi's testimony tended to show that the differences between Mr. Lau's invention and the prior art were insignificant. Indeed, the Court instructed the jury to consider differences over the prior art in the obviousness analysis. (D.I. 628 at 33). Medtronic should have been permitted to tell the jury that Mr. Khosravi – someone who was clearly skilled in the art of stent design in the late 1980's or early 1990's – believed that ACS's Multilink stent was nothing more than a series of connected Boneau rings. Thus, Mr. Khosravi's proffered testimony should have been permitted.

D. The Court's Exclusion of Certain of Lilip Lau's and William Hartigan's Testimony Was Erroneous and Prejudicial Because It Allowed ACS to Mislead The Jury

Of the many unusual features of this trial, perhaps one of the more unusual was ACS's contention that the testimony of the named inventors on its patents was irrelevant and should be excluded. Instead of bringing Mr. Lau to trial, ACS offered the testimony of Dr. Segal, Beverly Huss (who was not even at ACS at the time the Lau applications were filed) and Dr. Joel Kahn, all of whom testified directly or indirectly as to how revolutionary the Lau invention was. For example, Dr. Kahn testified that the

MultiLink stent was a radical advance and that the medical community was excited about the stent. (2/7/05 Trial Tr. at 247-250). Likewise, Ms. Huss and Dr. Segal testified what they considered to be the breakthroughs and advances of the three ACS inventors. (*Id.* at 308 and 408, 656). None of these witnesses, however, had personal knowledge of the work of the named inventors leading up to the conception of the invention, and ACS did not call any of its named inventors to testify about their invention.

Medtronic sought to introduce videotaped deposition testimony of inventors Mr. Lau and Mr. Hartigan, deposition testimony that told a very different story from that offered by Ms. Huss and Drs. Kahn and Segal.

The testimony that Medtronic sought to introduce from Mr. Lau related to: (a) the context and background of Mr. Lau's invention; (b) Mr. Lau's consulting agreements with ACS (which directly contradicted Ms. Huss' testimony that Mr. Lau is no longer employed by ACS); (c) the *entire* development story of ACS's stents (as opposed to the one-sided version ACS presented through its own witnesses) to show that Mr. Lau's invention was not new or groundbreaking; and (d) Medtronic's claim of invalidity (because one of ordinary skill in the art would have been motivated to combine the Boneau rings with the connectors found in the Palmaz-Schatz stent). (D.I. 596, Ex. B).

Similarly, Medtronic sought to introduce testimony from Mr. Hartigan that he had no knowledge of any major breakthroughs or radical advances that others contributed to the ACS invention; that he did not recall what most of the notes in his notebook referred to (including a reference to the "stent idea" in the relevant timeframe); that he did not recall what another reference in his notebooks – to the "stent concept" –

was or who came up with it; and that he had no recollection of speaking with Mr. Lau regarding making a stent with multiple ring connectors. (D.I. 604, Exh. B (3/30/04 Depo. Tr. at 108-109, 113-114, 120-121, 205-206)).

ACS objected, again accusing Medtronic of attempting to "reintroduce the trade secret case" and offering evidence that was "entirely irrelevant to the validity of ACS's patent claims." (D.I. 595 at 1; *see also* Trial Tr. at 345-346). As Medtronic explained, however, the proffered testimony in fact did not relate to meetings between Mr. Boneau or Mr. Lau "or anyone else at ACS." (Trial Tr. at 347). Rather, the testimony was relevant to contradict Ms. Huss's testimony about the innovativeness of the invention and to rebut ACS's one-sided development story. (*Id.* at 347-349).

Ultimately, the Court limited Mr. Lau's testimony to cursory information related to his consulting agreement. (Trial Tr. at 672-673). First, the Court found that an inventor's knowledge was irrelevant to "anything but inequitable conduct issues." (Trial Tr. at 350). On the issue of being able to tell a complete development story, the Court said:

> there's a huge difference in telling the development story in terms of a cardiologist who has discussed what products were available on the market for his use versus what was in the inventor's mind when he was actually going through the inventive process. Those are two difference development stories, and I don't think the one is relevant. Whether people allow each other to put that story on does not make any more legally relevant.

Id. Medtronic responded that it "was not putting Mr. Lau on to show what was in his head . . [but] for him to say what was and what was not obvious." *Id.* at 351. Respectfully, Medtronic does not believe that there are two separate development stories as the Court suggested. Rather, ACS used its product development story to argue that the

ACS invention was new and different from the prior art. It was this story that Medtronic should have been permitted to rebut. Because ACS opened the door, Medtronic's should have been permitted to offer Mr. Lau's and Mr. Hartigan's testimony to show a) what was in the prior art and, b) what Mr. Lau did. *Id.* Subsequently, the Court permitted certain limited testimony regarding the prior art but precluded Medtronic from introducing the remaining testimony necessary to complete the development story. Trial Tr. at 672-673; D.I. 596 at Ex. B. The Court similarly ruled that "Mr. Hartigan's testimony is not in . . ." (Trial Tr. at 1198), stating that "whatever relevance his testimony has is so intertwined with issues that I have deemed inappropriately brought into this court, that there's no way that I can let any of it in without leaving inferences that are inappropriate. And I find it of limited relevance." *Id.* at 1206.

As a result of the Court's rulings, ACS presented its (incomplete and inaccurate) side of the development story and was able to tell the jury its story of how its engineers conceived of the novel idea that led to the issuance of the Lau patents. Meanwhile, Medtronic could do nothing in response to ACS's evidence – it could not rebut it, it could not fill in the gaps and it could not educate the jury about the history and events that actually led up to ACS's development of its stent. In short, Medtronic (and the jury) had no choice but to accept ACS's story despite the fact that it was incomplete and wrong.

IV. MEDTRONIC SHOULD HAVE BEEN PERMITTED TO PRESENT EVIDENCE OF INCORRECT STATEMENTS MADE TO THE PATENT OFFICE

A. An Accused Infringer May Introduce Evidence Of Misstatements To The Patent Office During Prosecution To Help Rebut The Presumption Of Validity

A duly issued patent is presumed valid. 35 U.S.C. § 282. But that presumption can be rebutted by clear and convincing evidence of invalidity. *Surface Tech., Inc. v. U.S. Int'l Trade Comm'n*, 801 F.2d 1336, 1339 (Fed. Cir. 1986). Moreover, it is well-established that new evidence not considered by the Patent Office does eliminate, or at least reduce, the deference due to the Patent Office. As the Federal Circuit has stated:

> What the production of new prior art or other invalidating evidence not before the PTO does is to eliminate, or at least reduce, the element of deference due the PTO, thereby partially, if not wholly, *discharging* the attacker's burden, but neither shifting nor lightening it or changing the standard of proof. When an attacker simply goes over the same ground travelled by the PTO, part of the *burden* is to show that the PTO was wrong in its decision to grant the patent.

Am. Hoist & Derrick Co. v. Sowa & Sons, Inc., 725 F.2d 1350, 1360 (Fed. Cir. 1984).

Indeed, this Court has also held:

> A party challenging the validity of a patent has the burden to establish invalidity by clear and convincing evidence. In considering invalidity, the burden of proof under 35 U.S.C. § 282 is more easily carried when the offering prior art has not been before the Patent Office during the prosecution of the patent. ***EWP Corp. v. Reliance Universal, Inc.***, 755 F.2d 898, 905 (Fed. Cir. 1985).

Cordis Corp. v. Advanced Cardiovascular Sys., No. 97-550-SLR, 2000 U.S. Dist. LEXIS 4884, *10 (D. Del. Mar. 31, 2000). It stands to reason that the burden of proving invalidity can be even more easily carried when the party challenging the validity of the

patent can show that the Patent Office proceeded with its analysis based on mistaken or incorrect fact. This is precisely what happened in the *Surface Tech., Inc.* case.

In *Surface Tech., Inc.*, the accused infringer challenged the validity of the patent and prevailed in the ITC. On appeal, the patentholder argued that the Commission erred in invalidating the patent based only on its re-evaluation of the very same art that had been before the Patent Office. The Federal Circuit disagreed, and affirmed the ITC. Key to the Federal Circuit's reasoning were concerns over the credibility of certain affidavits filed during prosecution to bolster the claim that the subject matter sought was non-obvious: "From the prosecution history of the [patent in suit], it is clear that the affidavits [proffered by the applicant] were an important factor in overcoming the section 103 rejection. The subsequent testimony of [two of those affiants] compromised the strength and effectiveness of the affidavits." *Surface Tech., Inc.*, 801 F.2d at 1340-41. The questions raised about the accuracy of information submitted to the Patent Office, in that case, were part of the Federal Circuit's determination that substantial evidence supported the Commission's finding of invalidity. *Id.* The questions Medtronic sought to raise here were directly analogous and proper under *Surface Tech.*

B. ACS Made Material Misstatements To The Patent Office Which, Aside From Any Claim Of Inequitable Conduct, Caused The Lau Patents To Issue Erroneously

Like the accused infringer in *Surface Tech.*, Medtronic was prepared to come forward in this case with evidence that the Patent Office had materially incorrect information about the prior art in connection with the prosecution of the patents in suit. Medtronic believes that evidence would have established that the Patent Office acted on that misinformation when it allowed the asserted claims to issue. Specifically, during the

prosecution of the '154 patent, and to overcome the Examiner's rejection of certain claims based on anticipation by the prior art, ACS made inaccurate statements to the Patent Office about the characteristics of the Lau invention. For example, ACS made incorrect statements about the "outwardly projecting edges" and "appreciable shortening" in the Palmaz '417 patent in an attempt to distinguish these same features of '154 patent from the prior art.

As originally filed, claim 1 of the '154 patent claimed a longitudinally flexible stent with "outer wall surface having a plurality of outwardly projecting edges which form as said stent is expanded radially outwardly . . . ." (AX11 at 19). During the prosecution, the Examiner rejected claims 1-4 and 8-22 as anticipated by the teachings of the Palmaz '417 patent. The Examiner observed that Palmaz has outwardly projecting edges when it is expanded and has smooth edges when it is in a non-expanded state (***i.e.***, smooth before expansion; rough after).[2] (***Id.*** at 46). The Examiner also observed that Palmaz can be expanded radially without appreciable shortening. ***Id.***

On February 23, 1995, ACS amended claim 1 and "respectfully urged [the Examiner] that claims 1-4, and 8-22 . . . are patently distinguishable over the Palmaz '417 patent." (***Id.*** at 120). As amended, the claim included a longitudinally flexible stent comprising "an outer wall surface on said cylindrical elements, said outer wall surface

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[2] "Claims 1-4, and 8-22 are rejected under 35 U.S.C. §102(e) as being anticipated by Palmaz ('417). Palmaz teaches a stent 70 comprising: a plurality of cylindrical elements 71; . . . said stent having an outer wall which, as seen in fig. 10, has a plurality of outwardly projecting edges when said stent is in a fully expanded condition; said stent is smooth when in a non-expanded condition; . . . said stent can be expanded a small distance radially outwardly without appreciably shortening. It would appear that the outwardly projecting edges of Palmaz as seen in fig. 10 would be sufficient to embed in some vascular walls." (AX11 at 46).

being smooth prior to expansion of said stent and forming a plurality of outwardly projecting edges which form as said stent is expanded radially outwardly . . . ." (*Id.* at 119 (emphasis added)). ACS argued that Palmaz disclosed a smooth graft in both the expanded and unexpanded state (*i.e.*, smooth before expansion and smooth after expansion)). (*Id.* at 120). According to ACS, Palmaz amended his claims so that the outer surface was smooth before and after expansion, to overcome the Examiner's rejection based on the Ersek Patent. (*Id.* at 120-121). ACS asserted that, in contrast, its stent was smooth before expansion and rough after – the conclusion that the Examiner initially reached regarding Palmaz. (*Id.* at 121).

ACS further argued that figure 10 of the '417 Palmaz patent (which the Examiner concluded has outwardly projecting edges) demonstrated nothing more than a draftsman's rendition. ACS argued the irregularities of that rendition should not be relied upon as reflecting the actual structure. (*Id.* at 123). Thus, ACS argued that its invention was different because neither Palmaz nor Ersek taught the formation of outwardly projecting edges *during* expansion (because both were smooth before and smooth after). (*Id.*).

With regard to the Examiner's rejection based on the appreciable shortening taught by the Palmaz '417 patent, ACS said that "there is no teaching in the '417 patent that would support the rejection." (*Id.*). ACS told the Patent Office that the Palmaz stent must shorten somewhat when expanded due to its construction, which purportedly was in contrast to the ACS invention which it claimed *does not appreciably shorten during expansion*. (*Id.* at 122). In other words, ACS argued that the Palmaz stent appreciably shortens, while the ACS stent does not.

These statements to the Patent Office, it turns out, were completely incorrect. As concerns outwardly projecting edges, for example, Medtronic engineer Matthew Birdsall testified that that the Palmaz-Schatz stent was relatively smooth in its non-expanded state, like a straw with holes in it, and it had edges sticking out of it when it was expanded, like a dull cheese grater. (Trial Tr. at 882-884). In addition to this testimony, Medtronic attempted to introduce the testimony of Mr. Boneau about his experience with the Palmaz stent. Specifically, Medtronic offered testimony that Mr. Boneau personally examined the Palmaz stent in its expanded state and saw that it flared out at its ends. (D.I. 601, Trial Tr. at 1148). As Medtronic explained on February 11, 2005:

> [By Mr. Morisseau]: The fifth bullet point I think goes to an issue which is central to this case and that is what the prior art discloses.
>
> We're saying that one of the reasons that the – that ACS should not have gotten this patent is because the Palmaz/Schatz stents, in an expanded condition, had a rough exterior surface.
>
> Mr. Boneau will testify that, in 1989, he was in Argentina, and he examined and held in his hands several Palmaz/Schatz stents and ran his finger over those and it was something like a cheese grater and it had rough a rough exterior.
>
> And we have pictures of Palmaz/Schatz stents which are – which show that's what's known as outwardly projecting edges. That's what Mr. Boneau was running his fingers over.

(Trial Tr. at 1148.) The Court rejected Medtronic's argument because it believed that Mr. Boneau's testimony was expert testimony.

In relation to appreciable shortening, ACS's expert, Dr. Segal, testified that shortening of 10% or more was significant (*i.e.*, appreciable). (Trial Tr. at 495).

Medtronic's expert, Dr. Saigal, relying on data in the Handbook of Coronary Stents, testified that the Palmaz element had a percent shortening on expansion somewhere in the range of 2.5 percent to 5.3 percent. (Trial Tr. at 1324; DTX-103). Thus, under Dr. Segal's definition of appreciable shortening, the Palmaz stent did *not* appreciably shorten. Further, with regard to the Spiral Palmaz, the Handbook attributed shortening of 2.5 to 13.2 percent to that stent. (DTX-103). According to Dr. Saigal, because for most of these stents, the percentage of shortening is less than 10%, using Dr. Segal's definition, the Spiral Palmaz did not experience appreciable shortening. (Trial Tr. at 1325).

C. The Court's Ruling In Precluding Medtronic From Referring To ACS's Incorrect Statements Was Erroneous and Prejudicial

When Medtronic attempted to introduce evidence of the actual statements that ACS made to the Patent Office on the issue of appreciable shortening and outwardly projecting edges, ACS objected, relying on *Norian Corp. v. Stryker Corp.*, 363 F.3d 1321 (Fed. Cir. 2004), for the proposition that misstatements to the Patent Office are irrelevant to prove invalidity. *Norian* was not on point, however, and ACS's reliance on it was simply misplaced.

Norian Corp. involved an instruction by a district court that could have been read as permitting the jury to inquire into whether the examiner "really did understand what he was ruling.'" 363 F.3d at 1329. In *Norian Corp.*, the Federal Circuit, in dicta, stated that "the district court erred in instructing the jury that the presumption of validity varied with the jury's view of whether the examiner believed the applicant's

misstatements or otherwise did not 'properly focus on the prior art.'" *Id.* at 1329.[3] Medtronic, by contrast, did not seek to argue that misstatements to the Patent Office stripped ACS of the presumption of validity and certainly did not ask that the jury be instructed that such was the law. Rather, in meeting its burden, Medtronic properly sought to point out that the information on which the Patent Office relied in issuing the patent was incorrect, making the arguments it now presented to the jury novel ones, as is permitted under *Surface Tech., Inc.*

Medtronic should have been permitted to introduce evidence of the misinformation upon which the Patent Office acted in issuing the asserted claims. Medtronic should also have been permitted to argue, in effect, that the jury had different information about the Palmaz patent than did the Patent Office during prosecution of the Lau patents. It was prejudicial error to exclude this testimony.

V. THE COURT SHOULD HAVE LET THE QUESTION OF ANTICIPATION GO TO THE JURY

Medtronic's expert, Dr. Saigal, testified concerning the elements of various asserted Lau claims he found present in the so-called "Spiral Palmaz" prior art stent (the "Spiral Palmaz" or "'417 patent"). Dr. Saigal expressly testified that each and every element of the asserted claims of the '154 and '167 patents can be found in the '417 patent. A reasonable juror could have found, based on this testimony, that these claims were invalid due to anticipation. As a result, this issue should have been permitted to go to the jury.

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[3] The statement was dicta because the Court ultimately found that the instruction was harmless.

A. Dr. Saigal Identified All Of The Elements Of The Asserted Claims Present In The Spiral Palmaz Patent

At trial, Dr. Saigal testified that all elements of the asserted claims of the Lau '154 and '167 patents are found in the prior art. (Trial Tr. at 1276:25-1277:11, 1416:4-15). He then methodically walked through the evidence to illustrate which references reflected which elements. In so doing, Dr. Saigal established that the spiral-connector stent of the '417 patent disclosed each element of each asserted claim of the '154 and '167 patents.[4] Dr. Saigal's testimony concerning the remainder of the elements is set out in Exhibit C to this memorandum (a document that was filed with the Court before its ruling on anticipation).

B. Because Medtronic Presented Evidence From Which A Reasonable Juror Could Have Concluded That Spiral Palmaz Anticipated The ACS Patents, The Question Should Have Gone To The Jury

A court may render judgment as a matter of law on an issue at any time during a jury trial before the case is submitted to the jury, if a party has been fully heard on the issue and "there is no legally sufficient evidentiary basis for a reasonable jury to find for that party on that issue . . . ." Fed. R. Civ. P. 50(a). When reviewing a motion for judgment as a matter of law, however, the Court must view the evidence in the light most favorable to the *nonmoving party*. *IPPV Enters., LLC v. Echostar Communs. Corp.*,

[4] *See* 2/15/05 Trial Tr. at 1283:3-14, 1295:23-1296:18, 1299:7-1300:4, 1301:18-1303:16, 1303:17-1304:13, 1304:14-1305:11, 1308:4-1309:7, 1309:5-13, 1310:19-1320:6, 1323:11-1325:23, 1327:20-1329:19, 1336:21-1338:21, 1339:19-1340:23, 1345:1-19, 1354:25-1355:11, 1373:11-1375:4, and 1379:14-1380:16. (*See also* D.I. 627 (Medtronic's Revised Proffer Regarding Anticipation), attached hereto as Exhibit C).

No. 99-577-KAJ, 2003 U.S. Dist. LEXIS 3530 at *20 (D. Del. Feb. 27, 2003); *see also Mahurkar v. C.R. Bard, Inc.*, 79 F.3d 1572, 1576 (Fed. Cir. 1996). A court should grant a motion for judgment as a matter of law "*only if* the evidence demonstrates that there is no question of material fact for the jury and any verdict other than the one directed would be erroneous under the governing law." *Id.* (citing *Beck v. City of Pittsburgh*, 89 F.3d 966, 971 (3d Cir. 1996); *Macleary v. Hines*, 817 F.2d 1081, 1083 (3d Cir. 1987)); *Ericsson, Inc. v. Harris Corp.*, 352 F.3d 1369, 1373 (Fed. Cir. 2003) (stating that the court must look at evidence in favor of the non-movant and determine whether there is "sufficient evidence of record to support a jury verdict in favor of the non-movant.").

In circumstances analogous to those here, the Federal Circuit reversed a judgment as a matter of law by the district court where the facts could support the conclusion that the patent in suit was obvious, even though questions to the expert had not specifically focused on that particular legal theory. *Eolas Techs. Inc. v. Microsoft Corp.*, 399 F.3d 1325 (Fed. Cir. 2005). In *Eolas*, Microsoft framed the direct examination questions of its own expert in terms of anticipation, but then sought an instruction on obviousness as well. Conceding that Microsoft's experts had not been asked to opine specifically on obviousness, the court nonetheless held: "Although Microsoft's direct examination of [its expert] focused on anticipation, the information solicited from [him] might also support an argument of obviousness in the alternative." *Id.* at 1335.

Here, Dr. Saigal testified to the presence of each element of Claims 1, 4 and 12 of the '154 patent and Claims 5 and 8 of the '167 patent. Since there was a

sufficient evidentiary basis for a reasonable juror to find in favor of Medtronic on anticipation, the Court should have allowed the question of anticipation to go to the jury.

VI. MEDTRONIC WAS PREJUDICED BY THE INCONSISTENT APPLICATION OF THE COURT'S OBJECTIVE FINDING REGARDING THE STRUCTURE DISCLOSED IN THE PALMAZ '337 PATENT

As the Court is well aware, this case originally involved not only ACS's claims that Medtronic infringed the Lau patents, but also Medtronic's claims that ACS infringed the Boneau patents. In construing Medtronic's Boneau patents, the Court held that the prior art patent to Palmaz (U.S. Patent No. 4,776,337 (the "'337 patent")) disclosed a stent with a particular structure (circular bands joined by connectors). The Court's ruling pertained to the objective disclosure of Palmaz (and not just the particular application of that disclosure in the context of the Boneau patent prosecution). Nevertheless, the Court forbid Medtronic from raising that finding with respect to the Lau patents. In this regard, the Court committed prejudicial error by (a) refusing to instruct the jury as to the Court's finding, (b) forbidding Medtronic from presenting evidence consistent with the Court's finding, and (c) permitting ACS to present evidence that contradicted the Court's finding.[5]

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[5] Medtronic wishes to underscore for purposes of this discussion that it does not, in fact, agree with the Court's interpretation of the Palmaz disclosure. Nevertheless, Medtronic believes that, the Court having made the finding, it becomes the law of the case and should be applied consistently unless and until reconsidered by the Court or overturned on appeal.

A. The Court Made Objective Findings In This Case About How One Of Ordinary Skill In The Art Would Have Understood The Disclosure Of The Palmaz '337 Patent

On January 5, 2005, the Court granted ACS's motion for summary judgment of non-infringement of Medtronic's Boneau patents, finding no infringement of any claims of the Boneau patents literally or under the doctrine of equivalents. (D.I. 545). In finding no infringement under the doctrine of equivalents, the Court based its ruling on the doctrine of prosecution history estoppel. The Court held that Medtronic cannot assert the doctrine of equivalents because Mr. Boneau surrendered this subject matter in distinguishing his inventions from the Palmaz '337 patent. (*Id.* at 16).

In arriving at this conclusion, the Court found that the Palmaz stent "is made up of straight segments" that are "connected at their ends" to form a circular band. These circular bands are then connected to two straight segments "that attached adjacent circular bands." (D.I. 545 at 15). The Court held that one of ordinary skill in the art would have concluded that the subject matter of "connections between circular bands" was surrendered by Mr. Boneau in distinguishing the Palmaz prior art. (*Id.* at 15-16). Finding additionally that all of ACS's stents have "connections" that "attach circular elements together," the Court held that Mr. Boneau surrendered "this subject matter," and concluded that this precluded Medtronic from arguing the ACS's stents infringe under the doctrine of equivalents. (*Id.* at 16).

On January 20, 2005, Medtronic filed a motion *in limine* to preclude ACS from offering evidence or argument regarding the Palmaz patent that conflicted with the Court's findings concerning that patent (namely, that the Palmaz prior art disclosed a stent with "connections between circular bands"). (D.I. 563). Medtronic argued that the

Court's findings should be applied consistently to both the Lau and the Boneau side of the case. This would avoid multiple interpretations of Palmaz and maintain consistency thus avoiding the potential reconsideration of matters that have already been decided. *Id.* at 5. Medtronic intended to show that Palmaz, as construed by the Court as being comprised of circular bands with connections, anticipates, or at the very least, renders obvious the claims of the Lau patents.

ACS opposed Medtronic's motion and argued that the Court's ruling on the Palmaz disclosure was relevant only to the Boneau patents and had no bearing on the validity of the Lau patents. (D.I. 571 at 2). ACS also argued that it should not be estopped from making contradictory arguments because the Court's conclusion was part of its analysis of whether prosecution history estoppel applied to Boneau. (*Id.* at 3-6).

On February 1, 2005, the Court denied Medtronic's motion *in limine* stating that its analysis "was conducted in the specific context (the prosecution history of the Boneau patent) for the purpose of a limited issue (prosecution history estoppel)." (D.I. 578). On February 2, 2005, in precluding Medtronic from offering Dr. Saigal's supplemental expert report, the Court further stated that the Court does not consider "the Boneau case and the Lau case the same case." 2/2/05 Tr. at 4:6-7. Hence, the Court concluded, its "rulings in the Boneau case … has no place in this case. . . .[and its] ruling in that context is not binding and it does not mean didley-squat as far as [the Court] is concerned in this case." *Id.* at 11:23-12:1.

Thus, because the Court considered the Boneau and Lau cases to be completely separate, the Court admitted ACS's evidence regarding the Palmaz patent in the Lau case despite its conflicting finding on the same Palmaz patent in the Boneau case.

According to the Court, its findings regarding the Palmaz patent in the context of the prosecution history of the Boneau patents had no place in the Lau case.

B. Because Its Findings Regarding the Palmaz Patent Were Objective In Nature, The Court Should Have Applied Those Findings Consistently

"[T]he prosecution history should be *objectively* viewed from the perspective of *one skilled in the art*." *Pharmacia & Upjohn Co. v. Mylan Pharmaceuticals, Inc.*, 170 F.3d 1373, 1377 n.2 (Fed. Cir. 1999) (emphasis added)). The reason for this objective legal standard is found in the public notice function of the patent and its prosecution history. *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 234 F.3d 558, 564-65 (Fed. Cir. 2000) ("[t]he logic of prosecution history estoppel is that the patentee, during prosecution, has created a record that *fairly notifies the public* that the patentee has surrendered the right to claim particular matter as within the reach of the patent.").

As noted by the Court, "the prosecution history of a patent, as the *public record* of the patent proceedings, serves the important function of identifying the boundaries of the patentee's property rights." (D.I. 545 at 13). To reduce the substantial uncertainty of claim scope created by the doctrine of equivalents, competitors may *rely* on the prosecution history, the *public record* of the patent proceedings. *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 122 S. Ct. 1831, 1835 (2002). *See also Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 33-34 (1997). And, because competitors (*i.e.*, the public) may *rely* on the estoppel, the legal standard for determining what subject matter was relinquished during prosecution is an *objective* one, measured from the vantage point of what a competitor was reasonably entitled to conclude from the

prosecution history. *Zenith Lab., Inc. v. Bristol-Myers Squibb Co.*, 19 F.3d 1418, 1424 (Fed Cir 1994). This objective standard is usually articulated as what *one of ordinary skill in the art* would consider surrendered during the prosecution of the patent at issue. (D.I. 545 at 14, quoting *Augustine Med., Inc. v. Gaymar Indus., Inc.*, 181 F.3d 1291, 1298 (Fed. Cir. 1999)).

In ruling that findings regarding the Palmaz patent made in the context of interpreting the Boneau prosecution history are irrelevant to understanding the prior art to the Lau patents, the Court overlooked the objective standard of prosecution history estoppel. When the Court found that one of ordinary skill in the art, looking at potential prior art to the Boneau patent, would have viewed Palmaz to include "connections between circular bands" (D.I. 545 at 15), the Court's findings were objective in nature under the law of prosecution history estoppel. This means that the Court's findings as to the Palmaz patent must be applied uniformly regardless of whether the litigation involved only the Boneau patents or only the Lau patents. Indeed, this is only common sense. The Palmaz patent can have but only one disclosure.

ACS has argued that the Court should not apply rulings derived from its analysis of the Boneau prosecution history in order to understand the Lau patents. (*See, e.g.,* D.I. 571 at 3; *see also* Trial Tr. at 8:5-8). This argument, however, completely ignores the objective standard fundamental to the law of prosecution history estoppel. In fact, ACS omitted the key term "objective" when it misquoted the Court's summary judgment ruling in ACS's opposition to Medtronic's motion *in limine*. ACS stated, "As the Court noted, [determining the scope of the estoppel] requires *an examination* into the reason for, and nature of, the surrendered subject matter." (D.I. 571 at 3 (emphasis

added)). In fact, however, the Court actually referred to an *objective* examination. (*See* D.I. 545 at 13 (determining the scope of the estoppel "requires *an objective examination* into the reason for, and nature of, the surrendered subject matter")).

ACS's apparent oversight of the key term "objective" and the objective standard governing this inquiry is not surprising. If this Court had applied its objective findings of fact about the Palmaz patent consistently, Medtronic would have decisively refuted the overarching theme of ACS's trial presentation: that ACS was the first to come up with the idea of connecting short cylindrical elements to make a stent out of segments that, alone, would not themselves function as stents. On the contrary, if the Court's findings concerning the structure disclosed in the Palmaz patent are correct, than *Palmaz* was the first to make such a structure, and ACS's arguments were simply wrong. Medtronic was denied the opportunity to point this important fact out to the jury and, as a result, was unduly prejudiced.

Indeed, by allowing such conflicting findings to stand, Medtronic was deprived of fundamental due process. It is fundamentally unfair to interpret the very same patent one way for the purpose of limiting the scope of Medtronic's patents and an entirely different way for the purpose of preserving the validity of ACS's patents.

VII. THE COURT'S DECISION TO TRY CLAIM CONSTRUCTION TO THE JURY PREJUDICED MEDTRONIC

On the eve of trial, the Court withdrew its construction of the Lau patent claim terms "cylindrical element" and "undulating pattern" and directed the parties to present their evidence on the proper construction of these terms to the jury along with whatever infringement and validity evidence they deemed appropriate. (D.I. 587 (the

parties shall "present evidence as they deem appropriate in support of their respective interpretations" of the claim term)). As a result, the witnesses for each party were obliged to testify not only on how the facts as they saw them should be applied to alternative claim constructions, but also as to the reason the Court should adopt one construction over another.

At the close of all evidence, the Court acknowledged the closeness of the claim construction dispute: "I have to admit, I think both parties stated absolutely appropriate constructions in this case." *See* Trial Tr. at 1711. More specifically, after considering ACS's and Medtronic's responses to the Court's construction, the Court candidly noted:

> COURT: . . . I have to admit, I think both parties stated absolutely appropriate constructions in this case. I just felt it was more important for me under the latest iteration of what the Federal Circuit looks at to make the claim language consistent rather than trying to make the specification, prosecution history consistent with the claim language.
>
> So, that's where I went, but good argument. We'll let the Federal Circuit – what can I say? I don't have a clue which way the Federal Circuit will go on this. I wish I did. But I get paid the big bucks for drawing the final line – not the final line. The final line for the purposes of this jury. And the Federal Circuit will certainly review it.

Trial Tr. at 1711.

Then, on February 18, the Court instructed the jury on the proper claim construction of the terms "cylindrical element" and "undulating pattern." Trial Tr. at 1883. The construction contained no mention of U's, Y's or W's as advocated by Medtronic's witnesses and, as a result, implicitly signaled to the jury that the Court had decided that ACS's witnesses were "right" about claim construction (as well, perhaps, as

other issues) while Medtronic's were "wrong." The jury, of course, had none of this procedural background. Rather, it heard throughout the trial that Medtronic was urging that ACS had to prove a combination of U-, Y- and W-shaped elements while ACS urged that it did not. It also knew that the Court would select which construction to adopt.

Jurors in patent cases are often required to deal with complicated technology and detailed evidence from technical publications, scientific articles, and compilations of experimental data, as well as technical fact and opinion testimony. This litigation was no different in that regard. Unfortunately, by adopting ACS's construction at the conclusion of the trial, the Court effectively (though surely inadvertently) telegraphed to the jury the message that the key elements of Medtronic's infringement defense were either incorrect or irrelevant. There can be little doubt the jury saw this as indicating who was "right" and who "wrong" in this trial.

It is well-settled that patent claim construction is a matter of law exclusively for the court. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 979 (Fed. Cir. 1995). Directing the parties to present evidence going to claim construction to the jury (D.I. 587) – an issue it would not ever be called upon to decide – and then announcing the "loser" of the claim construction dispute by incorporating the proposed claim construction of the other into the jury's instructions, plainly tainted the jury. Because Medtronic was almost certainly prejudiced by that taint, the Court should grant Medtronic a new trial.

CONCLUSION

For all the foregoing reasons, Medtronic respectfully requests this Court grant its motion for a new trial.

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April 19, 2005
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CERTIFICATE OF SERVICE

I hereby certify that on April 19, 2005 I electronically filed the foregoing with the Clerk of the Court using CM/ECF, which will send notification of such filing to the following: Frederick L. Cottrell, III (cottrell@rlf.com), Stuart M. Grant (sgrant@gelaw.com), and Karen Jacobs Louden (kjlefiling@mnat.com).

I further certify that on April 19, 2005 I served copies of the foregoing on the following counsel in the manner indicated:

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